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The LARS: A ProDosed ADDroach f or FDA Evaluation
of Home Testing Products

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Introduction

Manufacturers first developed HIV home blood collection kits ten years ago. The kits are intended to be used by consumers in the privacy of their home to test for the presence of the human immunodeficiency virus (HIV). The collection kits instruct the consumer to obtain a blood sample, using the finger-prick method, and place the sample on the provided filter paper. Several days after mailing the sample to a laboratory, the consumer may obtain her test results by calling the manufacturer on the telephone. The manufacturers have proposed to make psychological counseling and referrals to medical facilities and social support available over the phone. Nevertheless, for reasons that will be fully discussed below, the manufacturers of the kits continue to await the Food and Drug Administration (FDA) approval required for the marketing and sale of the testing product.'

The blood collection kit is the only HIV home test for which a pre-market approval application has been filed with the FDA. Dr. Joseph D'Angelo, a Florida physician, developed a product that tests for HIV using an individual's saliva and enables the test-taker to interpret the results on his or her own. The kit instructs the consumer to obtain saliva from the mouth using the provided saliva collector, slip the collector into a plastic tube, and squeeze the saliva from the tube onto a membrane in a provided plastic cube. The presence of HIV causes the membrane to turn red. Dr. D'Angelo has chosen not to seek approval for over-the-counter sale in the United States due to the FDA's stringent requirements for approval of over-the-counter home test kits. Robert Nolin, *Blocked in the U.S., Home Test for AIDS is Going Overseas*, Seattle Times, Aug. 20, 1995, at L2.

The HIV home blood collection kits represent only one of many home testing products developed in the last several years. The past two decades have witnessed an exponential increase in the development and sale of over-the-counter medical home testing products. As of the late 1980s, medical home testing products constituted one of the most rapidly developing segments of the health-care market.² A 1987 survey conducted by the research firm Patient Searchlight found that twenty percent of all United States households used home testing devices each quarter³ and the market has grown since that time. New devices have been approved and many of the devices available in 1987 have increased in popularity, consequently, a more recent survey, conducted by Johnson & Johnson, found that 84% of Americans think home testing is more convenient than testing conducted at a doctors office or laboratory and 60% of American households have used at least one home medical test.⁴ Currently available home testing products include cholesterol monitoring kits, blood glucose monitoring kits, pregnancy tests, ovulation tests, and products that screen for colorectal cancer.

The popularity of home testing products is attributable to a number of factors and trends. First, many agree that

² Thomas A. Gossel, *Home Testing Products for Self-Monitoring*, 45 Am. J. of Hosp. Pharmacy 1119, 1119 (1988)

Th'o of Every Ten Households Now Use Home Diagnostic Tests, N527 Am. Pharmacy 15, 15 (1987).

Home Test Kits: Left to Our Own Devices, 21(1) Nary. Health Letter, Nov. 1, 1995.

Americans have adopted a take-charge attitude concerning health care that has extended to their desire to take part in

diagnosing certain conditions and monitoring treatment

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progress using home testing products. Originally seen in an emphasis on exercising and eating right, the current trend

for Americans to take a more active role in managing their health has become apparent in their use of home testing products **6**

Second, demographic trends have contributed to the increased popularity of home testing. Many of the conditions tested for using home testing devices disproportionately affect those over fifty, the fastest growing segment of the population.⁷ Thus, it is unsurprising that the average home test user is a middle aged individual.⁸ The mean age of consumers using the home tests in the Patient Searchlight study was 55 for colorectal cancer tests, 54 for glucose in urine tests, 53 for blood pressure tests, and 47 for blood glucose tests.⁹

Finally, some of the popularity of home testing products may be attributed to their potential to save consumers both

s Frank E. Young, *A Doctor's Advice on Self-Care*, FDA

Consumer, Dec. 1988, at 6. *See also* Stephen Joel Coons, Ph.D. & Joseph L Fink III, J.D., *The Pharmacist, the Law, and Self-Testing Products*, Am. Pharmacy, Nov. 1989, at 35.

6 Young, *supra* note 5.

Factors Converge to Bolster Sales of Home Test Kits, Chain Drug Rev., Dec. 5, 1994, at 48.

B Margaret Reich, *The ABCs of HMTs (Home Medical Tests)*, Journal of AOA, Dec. 1987, at 130, 130; *Two of Every Ten Households*, *supra* note 3.

Two of Every Ten Households, *supra* note 3.

time and money. Negative results allow patients to forgo unnecessary visits to and examinations by physicians. Home testing products are less expensive than tests performed by physicians and have become even cheaper in recent years. For example, in the late eighties blood glucose monitors cost as much as two hundred dollars, whereas today consumers may

purchase the monitors for as little as fifty dollars in out

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of pocket expenses. The cost of home cholesterol tests has recently fallen as well.¹¹ As more and more competitors enter the home test market, prices are likely to continue to fall, making the products even more affordable and more appealing to consumers.

In addition to the increasing popularity of home testing products, the growth of the market is attributable to the discovery of monoclonal antibodies. **12** Monoclonal antibodies

are cells that can recognize and bind to virtually any type

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of molecule. They can detect specific chemical substances

in extremely small quantities and are used in many home testing products to selectively bind to specific target antigens. They allow for increased sensitivity and specificity of devices such as pregnancy and ovulation kits,

10 *Factors Converge to Bolster Sales of Home Test Kits*, *supra* note 7.

ChemTrak recently lowered the price on its over-the-counter cholesterol test in order to spur sales. **22** Gray Sheet No. 1, Jan. 1, 1996.

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Gossel, *supra* note 2, at 1120.

13 *Home Test Market Expected to Top \$1 Billion by 1992*, Drug Topics, Sept. 21, 1987, at 58.

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leading to the attainment of increasingly accurate test results **14**

This paper critiques the manner in which the Food and Drug Administration uses its discretionary authority to regulate the sale of home testing products. Part I provides the legal framework for FDA approval of home testing products and emphasizes the discretionary authority enjoyed by the agency. In particular, Part I details the responsibility of the FDA to ensure that marketed devices are both safe and effective. Part II details the manner in which the FDA has used its discretionary authority to prevent the sale of HIV blood collection kits. It supports the argument that the current system of regulation is marked by the FDA's excessive use of its statutory discretion.

Part III argues for a more appropriate system of FDA evaluation of home testing products, one which focuses more squarely on the accuracy of the results achieved by laypersons using the product. It proposes that the FDA establish a standard rate of accuracy that all home testing products used by laypersons would be expected to achieve. Those which satisfy the layperson accuracy rate standard (the LARS) and for which heightened accuracy rates are not reasonably feasible given the then current state of science

Sensitivity refers to how well the test detects small quantities of the target substance, at a level that permits accurate assessment of the condition. The term specificity is qualitative; it reflects the idea that the product should not detect substances other than the one being tested for. Gossel, *supra* note 2, at 1120.

would be approved by the FDA for sale to the public. This standard should operate as a strong presumption that any home testing product not satisfying the LARS is not effective and thus not marketable. The presumption, however, should be rebuttable. Where the FDA determines that the introduction of the product would present a significant benefit to public health despite its failure to satisfy the standard, the FDA should approve the home testing product. The FDA should exercise self-restraint in using its discretionary authority so as to better ensure that safe and effective home testing products that are beneficial to public health are approved, while continuing to prevent the sale of products that are unsafe or ineffective. Finally, Part III demonstrates that an analysis of the HIV blood collection kits under the proposed system would properly have led to a much more speedy approval of the kits.

I. The Legal Framework

The Food and Drug Administration regulates home testing products as medical devices. A medical device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or

prevention of disease in man. ~ Prior to the enactment of the Medical Device Amendments of 1976, manufacturers of medical devices could market those devices without any premarket oversight or approval by the Food and Drug Administration. FDA authority was limited to the seizure or recall of marketed devices upon evidence that the devices were unsafe or ineffective. The FDA did not have the authority to monitor or limit the market introduction of such devices.

In the decades following the enactment of the Federal Food, Drug, and Cosmetic Act of 1938, the lack of regulatory authority allowed for the sale of numerous ineffective or unsafe devices. The elimination of such devices from the market by the FDA was often costly and slow. One dangerous device the FDA eliminated from the market in the 1960's was known as the Relaxicisor. The Relaxicisor purportedly aided weight loss by sending shocks through the muscles. The shocks, however, caused serious bodily injury. Nevertheless, the elimination of the product from the market cost half a million dollars and required five years of court proceedings.¹⁶ Similarly, the elimination of a device known as the Diapulse required a total of eight years of FDA activity.

Section 201 of the Federal Food Drug and Cosmetic Act; 21 U.S.C. s. 321.

¹⁶ See *S. Rep.* No. 33, 94th Cong., 2d Sess. (1976).

¹⁷ *Id.*

In 1970, the Dalkon Shield, an intrauterine device, was introduced to the market. Within five years, the device had been linked to numerous deaths, miscarriages, and lawsuits. Following the removal of the Dalkon Shield from the market, Congress sought to prevent the occurrence of a similar tragedy in the future. Congress believed that many of the deaths and much of the illness attributed to the use of the Dalkon Shield could have been prevented if legislation such as the Medical Device Amendments had been in effect. **18** In enacting the Amendments, Congress granted the Food and Drug Administration broad discretion to regulate the sale of medical devices in order to assure the reasonable safety and effectiveness of medical devices intended for human use.⁹

To this end, Congress granted the FDA the authority to classify all medical devices into one of three categories based upon the degree of risk to the public health and safety represented by each individual device or class of devices.²⁰ Devices that do not require stringent controls to assure safety and effectiveness are classified as Class I devices. Class II devices are those requiring more special controls than Class I devices. Class III medical devices are devices for which general controls are not sufficient to assure safety and effectiveness and there is not sufficient information to establish a performance standard, as well as those found not substantially equivalent to a device placed

is *Id.*

H.R. Conf. Rep. No. 1090, 94th Cong., 2nd Sess. (1976). **20** 33.

S. Rep. No.

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on the market prior to the enactment of the Amendments. A Class III device may only be marketed if the FDA grants the device pre-market approval for safety and effectiveness or excepts the device from the pre-market approval process either by finding the device is substantially equivalent in design and function to a device on the market prior to the enactment of the Medical Device Amendments or grants an investigational device exemption and thus permits the device to be tested on humans.²² Therefore, a Class III medical device that is not found to be substantially equivalent to a device marketed prior to the enactment of the Amendments requires FDA pre-market approval to assure reasonable safety and effectiveness.²³

The text of the Medical Device Amendments provides the FDA with guidance as to the proper methods for determining the safety and effectiveness of a device. The statute states that safety and effectiveness are to be determined

- (A) with respect to the persons for whose use the device is represented or intended,
- (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and
- (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.²⁴

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Peter Barton Hutt & Richard A. Merrill, Food and Drug Law 745 (2d edition, 1991)

²² *Bokis v. Am. Medical Sys., Inc.*, 875 F.Supp. 748 (W.D. Okla. 1995)

²³ *Id*

²⁴ Section 513 of the Federal Food Drug and Cosmetic Act; 21 U.S.C. s. 360c.

Furthermore, the statute indicates that manufacturers should produce evidence of effectiveness by

.well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the

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device.

An examination of the legislative history of the Medical Device Amendments provides further insight to Congress' view regarding the proper determination of safety and effectiveness.

Especially relevant in the context of home testing devices, the legislative history indicates that the Committee on Labor and Public Welfare, to which the bill was referred, was impressed by testimony that the skill of the user of the device is very important in determining its safety and

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effectiveness. The Committee intended that the evaluation

of the safety and efficacy of a device be done in relation to the skill of the person who utilizes it.²⁷ A device that is safe only when used by eminently qualified specialists should be restricted to use by those specialists.²⁸ Accordingly, different criteria apply when a manufacturer seeks approval for a device for home use by laypersons than when approval is sought for the restricted use by professionals only.

25 *Id*

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S. Rep. No. 33.

27 *Id*

28 *Id*

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The Medical Device Amendments provide the FDA with enormous discretion in determining whether a device is both

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safe and effective. To ensure safe and effective devices,

Congress authorized the FDA Secretary to use all of the authorities contained in [the] Act in any combination deemed necessary to protect the public health and safety.³⁰

This broad grant of discretion has been underscored by the District of Columbia Circuit Court. In *Contact Lens Manufacturers Association v. FDA*, the court referred to FDA discretion under the Medical Device Amendments as broad and considerable.³¹ It noted,

[W]e are mindful that... generalist courts see through a glass darkly and should be especially reluctant to upset an expert agency's judgment that a party has failed to adduce sufficient scientific proof of safety and effectiveness.³²

Less than two months later, in *General Medical Company v. United States Food and Drug Administration*, the court upheld both the FDA'S classification of General Medical Company's Drionic antiperspirant device as a Class III medical device and its refusal to reclassify the device to Class I status.³³

29 The legislative history of the Medical Device Amendments

evinces a Congressional desire that the FDA enjoy regulatory authority over the sale of devices in a manner more similar to the authority the FDA enjoys in regulating drugs for safety and effectiveness. *Id.*

30 *Id.*

Contact Lens Mfr. Ass'n v. Food and Drug Admin. of the Dep't of Health and Human Serv., 766 F.2d 592, 594, 247 U.S. App. D.C. 102, 104 (D.C. Cir. 1985), *cert. denied*, 474 U.S. 1062, 106 S.Ct. 810, 88 L.Ed.2d 784 (1986)

(denying manufacturer's petition for review of the FDA's decision not to reclassify lenses in accordance with its own reclassification proposal).

32 *Id.* at 599-600, 247 U.S. App. D.C. at 109-10. *Gen. Medical Co. v. U.S. Food and Drug Admin.*, 770 F.2d

The court held the FDA was within its broad discretion when it concluded that the manufacturer had failed to show the device to be safe and effective due to a potential unreasonable risk of illness or injury, where the benefits of the device were essentially impossible to determine and the harms were small but clearly demonstrated.³⁴

In 1988, the FDA Center for Devices and Radiological Health (CDRH), the office responsible for regulating the introduction and sale of devices, released a guidance document to assist prospective manufacturers, producers, and marketers of home testing kits and home use mail-in specimen collection kits in complying with existing regulations. The document, entitled *Assessing the Safety and Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions*, reflected CDRH's views of the key points it would consider in determining the safety and effectiveness of home testing

devices.³⁵ CDRH declared test performance to be a key factor

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in determining safety and effectiveness. It considered the ability of laypersons to perform the test to be critical.

Recognizing that home testing products are used by laypeople who lack medical and technical training, CDRH declared

214, 248 U.S. App. D.C. 158 (D.C. Cir. 1985).

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Id. at 221, 248 U.S. App. D.C. at 165.

Center for Devices and Radiological Health, Food and Drug Administration, Assessing the Safety and Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions, at 2 (1988).

36 *Id.* at 2-3.

an analysis of the risks and benefits of a device to be inherent in the evaluation of safety and effectiveness.³⁷ CDRH further determined the key points to be the performance of the device, the risks and benefits of introducing the device to the market, the proposed labeling, and the results of performance studies. It declared its purpose in outlining the uniform evaluation criteria to be the assurance that home testing products are regulated in a consistent fashion and that consumers are provided with reliable, useful, and adequately labeled products.³⁸

In evaluating home testing products, the FDA has considered evidentiary assurances of accuracy, clinical benefit to the patient or to public health, the benefit to the consumer of using a home test rather than a test for professional use only, the consequences of inaccurate results, and the risks to both the user and society of false or unclear results.³⁹ It has followed the evaluation approach adopted in the 1988 guidance document.

Nevertheless, the FDA's decisions regarding home testing device approval continue to appear somewhat unpredictable. The FDA has never specified to what extent accuracy rates achieved by laypersons may deviate from those achieved when the devices are used by professionals. It has never fully detailed the factors to be considered in the analysis of the risks and benefits of a device. It does not limit the

~ *Id.* at 5.

³⁸ *Id.* at 2.

~ washington Drug Letter, Jun. 29, 1987.

factors it may consider, but rather considers any factor deemed appropriate or relevant at the time.

The Office of the Inspector General of the Department of Health and Human Services, after closely studying FDA. evaluation of home testing products, found that the FDA had been very cautious in using its discretionary authority to approve the devices.⁴⁰ Stated differently, the FDA had been very ambitious in using its discretion to refuse or deny approval to newly developed home testing products. The FDA had successfully prevented the sale of unsafe or ineffective devices, however it had also prevented the sale of safe and effective devices such as the HIV home blood collection kits.

II. The FDA Refusal to Approve HIV Home

Blood Collection Kits

The Food and Drug Administration has used its authority and discretion to prevent the over-the-counter sale of HIV home blood collection kits. Manufacturers first notified the Food and Drug Administration of their intent to market blood collection kits for use in detecting HIV ten years ago.⁴¹ At that time, the FDA determined that such kits constituted Class III medical devices not substantially equivalent to

⁴⁰ See *Office of Inspector Gen., Dep't of Health and Human Serv., Home Testing Devices: FDA Clearance and Monitoring Activities*, at ii (1989).

⁴¹ Blood Collection Kits Labeled for Human Immunodeficiency Type 1 (HIV-1) Antibody Testing; Home Test Kits Designed to Detect HIV-1 Antibody; Open Meeting, 54 Fed. Reg. 7279, 7280 (1989).

those on the market in 1976, thus requiring the manufacturers to submit pre-market approval applications showing the kits to be both safe and effective.⁴²

Then, in a 1988 letter written by Paul Parkman, the Director of FDA's Biologics Center, the FDA informed seventeen manufacturers wishing to market HIV home tests that it did not approve of such home use at that time.⁴³ The letter declared that the FDA would accept pre-market approval applications for professional use AIDS tests only. The Gray Sheet wrote that this decision was reportedly made in light of the concerns of a number of government health officials about the misuse of test information and the possibility of inaccurate test results.⁴⁴

One year later, the FDA arranged a public meeting to discuss the issues surrounding blood collection kits, including those for use at home by non-professionals. The meeting was held on April 6, 1989 at the National Institutes of Health. Its purpose was to allow public comment on the risks and benefits of both HIV home blood collection kits and HIV testing products that would provide for lay users to interpret the results of the test.⁴⁵ A major concern shared by the participants was the adequacy of the telephone counseling. Other concerns included the possible contamination of blood specimens while in transit and the

⁴² *Id.*

⁴³ 14 Gray Sheet No. 15, Apr. 11, 1988; 54 Fed. Reg. 7279 at 7280.

⁴⁴ *Id.*

⁴⁵ *Id.*

issue whether the FDA should permit home tests intended to diagnose infectious diseases at all.⁴⁶

Shortly thereafter, the FDA sent a letter to those expressing an interest in marketing such devices which stated that it would accept applications for pre-market approval of HIV blood collection kits for home use and was willing to review with the manufacturer the suitable information to be included in the application to show the safety and effectiveness required of all medical devices.⁴⁷ This ended the agency's two year refusal to accept applications for premarket approval of HIV home test kits. Nevertheless, the approval criteria adopted in 1989 were reaffirmed as valid.⁴⁸

The criteria included requirements that the kits be labeled and marketed for professional use only within a health care environment and provide for the collection of blood by one permitted by state or local authorities to perform such procedures. Furthermore, all test results had to be reported directly to a professional health care provider for the purposes of both relaying the test results to the individual tested and counseling the individual. Thus, the position of the FDA was inconsistent. The agency announced that it would accept applications for pre-market approval of HIV home blood collection kits, however¹ it

⁴⁶ *Id.*

⁴⁷ ~ Blood Collection Kits Labeled for Human Immunodeficiency Virus (HIV-1) Antibody Testing; Availability of a Letter for Interested Persons, 55 Fed. Reg. 30982, 30983 (1990)

⁴⁸ *Id.* at 30982.

reaffirmed as valid the requirement that the kits be labeled and marketed for professional use only.

Four years later, on June 22, 1994, the Blood Products Advisory Committee conducted an open discussion at which time it revisited the question of over-the-counter blood collection kits for use in detecting HIV. The Committee premised its revisitation of the issue on recent scientific and technological developments and the changing nature of the HIV epidemic.⁴⁹ Over 60 members of the public presented their views to the Committee with the result that the FDA did revise its policy regarding HIV home test kits.⁵⁰

By this time, a majority of the Committee members had begun to view FDA approval of such kits as inevitable.⁵¹ James Bowman, M.D., a Committee panelist present at the June 1994 meeting, expressed the view of many members of the panel when he said,

I think the benefits far outweigh the disadvantages and I am convinced..., that there will be individuals out there who will be identified, who are outside of the system, who are not being identified in the present inadequate system.⁵²

The panelists saw the kits as a necessary weapon in the fight against the AIDS epidemic, since the introduction of the kits would likely lead to an overall increase in the number of people tested for the virus. This increase in the number of individuals tested would enable those individuals to both

~ Advisory Committee Meeting; Amendment of Notice, 59 Fed. Reg. 29814 (1994)

⁵⁰ 20 Gray Sheet No. 26, Jun. 27, 1994.

~~ *Id.*

⁵² *Id.*

seek early medical treatment and regulate their activities so as not to infect others.

For this reason, the panel focused the discussion on when and in what manner the tests should be marketed.⁵³ The majority agreed that studies should be undertaken to evaluate user demographics and pre- and post-test counseling. This recommendation of pilot studies was generally understood to be a call for post-marketing studies, as opposed to premarket studies.⁵⁴

The following fall, the FDA seemed to have moved closer to approving an HIV blood collection kit for home use. FDA Deputy Commissioner Mary Pendergast stated at a meeting with industry regulatory officials that as far as FDA is concerned, home-based collection kits for the HIV virus do not pose major regulatory difficulties if they are accurate and people get counseling.⁵⁵

On February 23, 1995, the Food and Drug Administration officially announced in the Federal Register that over-the-counter home specimen collection kits for HIV testing may be approvable.⁵⁶ It further announced that manufacturers should include information in the pre-market approval applications on a number of specified issues.~ First, the

~ *Id.*

~ *Id.*

~ 20 Gray Sheet No. 41, Oct. 10, 1994.

s6 Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV-1 and/or NIV-2) Antibody Testing; Revisions to Previous Guidance, 60 Fed. Reg. 10087, 10087 (1995)

~ *Id.*

SB *Id.*

~ *Id.* at 10087-88.

agency declared that appropriate pre-clinical studies and clinical trials conducted under an approved investigational device exemption should validate all technical aspects of the kits and demonstrate the reproducibility, sensitivity, and specificity of test results in comparison with an approved. professional use system for the collection and testing of blood or any other appropriately validated specimen. In addition, manufacturers should conduct field trials in a population resembling the intended consumer market. Other issues to be analyzed during clinical trials included lay comprehension of the instruction booklet, lay competency in conducting the finger-prick, and the manufacturer's safe handling, transport, and disposal of the blood specimens. Furthermore, the FDA required that the manufacturer include documentation of quality assurance regarding the manufacture of the kits and the testing of the specimens in a laboratory in compliance with current requirements. The manufacturer should further show maintenance of test records and a system for reporting adverse events or device failures.

Second, the testing for all specimens collected using the home specimen collection kits should include the use of a licensed screening test for HIV antibodies.⁵⁹ Those specimens repeatedly reacting to the screening test, thus indicating the likelihood that they contain the virus, should then be tested using a licensed more specific test.

Third, the test results should be reported to those using the device by counselors trained in HIV notification and counseling. The counseling should include referral to medical and social support services.

Lastly, the manufacturer should consider collecting and divulging demographic data to the FDA where appropriate. In addition, the manufacturer should discuss proposals for appropriate post-market studies to assess the public health impact of the product.⁶⁰

The FDA theoretically would approve those devices that satisfied the above criteria. To date, three manufacturers have submitted applications to the FDA for pre-market approval of HIV home test kits, all of them blood collection kits. Johnson and Johnson has submitted an application to market Confide; Home Access Health Corp. has submitted a premarket approval application for a home collection kit named HIV-Test; and ChemTrak, seeks approval for the HIV-1 Home Check. Many have referred to FDA approval of HIV at-home blood collection kits as a virtual certainty. ,~**61**

As of last year, Confide was widely considered to be the

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HIV home test kit closest to gaining FDA approval. However, ten years after the development of HIV home blood collection kits, the FDA continues to review the manufacturers' premarket approval applications as the manufacturers await

60 *Id.* at 10088.

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See, e.g., Charles Marwick, *Home Testing Kits for HIV Apt to Get FDA Approval*, 273 JAMA 908 (1995).

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See, e.g., *Test Kits Usher in High-Tech Health Care*, OTC Market Report Update USA, Aug. 1, 1995.

approval. Thus, the FDA continues to use its gate keeping power to block the sale of HIV home blood collection kits.

III. A Proposed Approach

The time is ripe for the FDA to adopt a new approach in approving home testing devices. As detailed above, the current approach is overly cautious and allows FDA officials to deny approval whenever they feel that some harm, no matter how small, may result from the sale of the device. The time has come for a more coherent policy that more efficiently and speedily leads to the approval of devices that will benefit the public.

The Food and Drug Administration could better protect public health by focusing more squarely on the accuracy of the home test results obtained by laypersons. The FDA has declared test performance to be a key factor in determining the safety and effectiveness of a device.⁶³ However, the importance of layperson accuracy warrants an approach that makes layperson accuracy *the* key factor.

Home testing products have value only if they produce accurate results. Inaccurate devices do the public no good and can potentially do great harm. False positives cause unnecessary anxiety and stress and may cause consumers to cease precautionary behavior. False negatives are likely to

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Center for Devices and Radiological Health, supra note 35, at 2-3.

lead to delayed treatment, thus permitting the disease or condition to progress and increase in seriousness.

An approach focused on accuracy should involve the use of an accuracy standard. The FDA should establish a layperson accuracy rate, that is, a rate of accuracy that all newly developed devices must achieve when used by laypersons to be safe and effective for over-the-counter sale. This layperson accuracy rate standard (LARS) should be high enough that laypersons may rely on the test to produce accurate results, but low enough that it is satisfiable. This would necessarily involve a bright line test that should be made known to the health care and manufacturing industries. Before approving a newly developed home testing device, the FDA should demand to see evidence that laypersons using the device will achieve accurate results in proportion to the LARS. Manufacturers should be required to conduct clinical studies that evidence the satisfaction of the LARS.

In adopting the LARS approach, the FDA should be careful to avoid a race to the bottom. The FDA should employ the LARS as a satisfactory accuracy rate for all newly developed devices for which higher rates of accuracy are not reasonably feasible given the then current state of science. Thus, the FDA would require higher rates of accuracy for newly developed devices for which higher rates of layperson accuracy may reasonably be achieved. In many respects, the LARS system is analogous to the negligence system in which a minimum level of performance is required, yet individuals who

represent themselves as expert in a number of specified contexts must satisfy a higher standard of care or performance where possible. Where similar devices have been approved by the FDA that exceed the LARS, subsequent devices would be required to exceed the LARS as well, since the development of the previous device is proof that the achievement of a higher layperson accuracy rate is reasonably feasible.

Admittedly, determining the precise LARS to be adopted will be difficult. To some degree, any time an agency or organization adopts a numerical standard or cutoff, its choice may be said to be somewhat arbitrary. Nevertheless, the adoption of a LARS would greatly improve the process of FDA home testing device evaluation. In setting the LARS, the FDA should recognize that even laboratory results are not error free. Although generally in agreement that laboratory test results are not error free, experts disagree as to the prevalence of error.

In studying the margin of error in scientific analysis, Edward Imwinkelried has written that extensive hard evidence exists of a substantial margin of error in modern forensic analysis.⁶⁴ Although, Imwinkelried generally focused his research on forensic laboratories, his finding of an alarmingly high incidence of misanalysis,⁶⁵ is relevant in

⁶⁴ Edward Imwinkelried, *The Debate in the DNA Cases over the Foundation for the Admission of Scientific Evidence: The Importance of Human Error as a Cause of Forensic Misanalysis*, 69 Wash. U. L.Q. 19, 27 (1991).

⁶⁵ *Id.*

the context of home testing products as support for the proposition that testing results are likely to contain some incidence of human error even when obtained by experts.

Imwinkelried found that erroneous test results often result from improper procedure. He asserted that TMeven in the case of relatively simple forensic techniques... it is vital that the forensic scientist follow correct procedure.⁶⁶ At least one study found the analyst's use of improper test procedure to be the factor most frequently contributing to inaccurate results.⁶⁷

Numerous scholars have cited the problem of medical laboratory error,⁶⁸ however, little concrete data existed as to its actual prevalence until the definitive results of a study on the quality of clinical laboratory testing were published in the Journal of the American Medical Association this past February.⁶⁹ In this study, primary care clinicians reported and described all laboratory problems detected

during a 6-month period in 1993.~~ The clinicians reported a total of 180 problems, 49 of which had an effect on patient

⁶⁶ *Id.* at 30.

⁶⁷ *Id.* at 32.

⁶⁸ Robert Miceli asserted that laboratory tests are prone to

errors because of limitations in accuracy; errors of observation and interpretation; miscalculations; transcription errors; errors in specimen collection and handling; and even the remote possibility of a mix-up of specimens in the laboratory. Robert G. Miceli, M.D., J.D., *Deprivation of Due Process for Physicians: The Failure to Diagnose Cause of Action*, 33 St. Louis U. L.J. 859 (1989)

⁶⁹ Paul A. Nutting et al., *Problems in Laboratory Testing in Primary Care*, 275 JAMA 635 (1996)

⁷⁰ *Id.*

care. The researchers estimated the frequency of laboratory problems to be approximately 1.1 per 1000 patient visits.⁷¹ Since generally one third of all patient visits involve laboratory testing, the study concluded that problems with laboratory testing occurred in 3.4 out of 1000 patient visits involving such testing.⁷² Consequently, the study suggested that problems with laboratory testing that are apparent to the practice are relatively infrequent.⁷³

The study found however that patient care [was] affected in about 27% of [the] occurrences of problems.⁷⁴ Information about the impact of the problems was available in half the cases involving an effect on patient care. Ten had a significant effect on patient care, meaning that the problem affected the diagnosis or treatment.⁷⁵ The reported impacts varied from the inconvenience of repeating a test to a delayed diagnosis of HIV infection and an unnecessary hospitalization. **76**

Thus, it appears that, in contrast to previous concerns, medical testing conducted by experienced laboratory technicians involves a fairly low rate of human error. For this reason, in setting the LARS, the FDA should recognize that home testing by laypersons is likely to be substituted for more accurate testing and that although not error free,

71 *Id.*

72 *Id.*

~ *Id.*

~ *Id.*

~ *Id.*

76 *Id.*

professional testing generally involves little error. The FDA should adopt a LARS that does not permit home testing accuracy to fall much below professional testing. The FDA should use its expertise to determine a LARS that although recognizing that some error is inevitable, demands a high standard of layperson accuracy.

By measuring the accuracy of the device in terms of the rate of accurate results obtained by laypersons, the scheme satisfies the Medical Devices Amendments requirement that safety and effectiveness be determined with respect to the persons for whose use the device is represented or intended.⁷⁷ By specially evaluating the devices as home testing products, the scheme satisfies the statutory requirement that the FDA determine safety and effectiveness with respect to the conditions of use... recommended or suggested in the labeling.⁷⁸ Finally, by setting a sufficiently high LARS, the approach weighs the probable risk of harm that would result from laypersons obtaining inaccurate results with the benefit to health from increased testing for medical conditions and disease.⁷⁹

Manufacturers should test layperson accuracy by conducting clinical trials. The Medical Device Amendments

See Section 513 of the Federal Food Drug and Cosmetic Act; 21 U.S.C. s. 360c.

⁷⁸ *Id.*

~ The Medical Device Amendments provide that safety and effectiveness are to be determined weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. *Id.*

provide that evidence of accuracy should be evinced through well-controlled... clinical investigations.⁸⁰ The FDA should continue its practice of placing considerable importance on the outcome of the consumer field evaluation II] in assessing the safety and effectiveness of home-use IVDs and recommending that manufacturers conduct performance studies to establish proper performance of the home testing product both in the laboratory and when used by laypersons.⁸¹

The individuals chosen by manufacturers for participation in clinical studies should resemble the general population for whom the device is intended. With two exceptions, the participants should generally resemble a cross-section of society in terms of age, gender, education, and socio-economic background. First, devices, such as pregnancy tests, intended for use by members of a single gender only should be tested by people of that gender. Second, devices geared to a certain age category, such as the colorectal cancer kits, should be primarily tested by people of that age.

FDA approval of home testing products is properly based on the provision of evidence of layperson accuracy. The issue of accuracy remains a live one as many medical experts continue to doubt the accuracy of the results achieved by laypersons using home testing products and medical studies

⁸⁰ See Section 513 of the Federal Food Drug and Cosmetic Act;

²¹ U.S.C. s. 360c.

⁸¹ *Center for Devices and Radiological Health*, *supra* note 35, at 10.

continue to provide evidence substantiating these concerns. For this reason it has been said, [Milany home test kits are as accurate as lab tests - if performed correctly. And that's the catch.⁸²

Numerous studies have concluded that laypersons using home testing products achieve significantly less accurate results than health professionals and medical experts. Even home pregnancy tests, widely viewed as some of the most accurate home testing products, continue to be criticized as prone to error. ⁸³ Home pregnancy kits test for the presence of the hormone known as human chorionic gonadotropin (HCG) produced by the placenta and secreted in urine during pregnancy.⁸⁴ Modern tests contain monoclonal antibodies that can detect minute traces of HCG, allowing for earlier

⁸² Mark L. Fuerst, *The Home Test Movement Shifts into High Gear*, Medical World News, Feb. 11, 1985.

⁸³ Some have argued that criticisms by medical professionals

of the home testing trend stem in part from fears of reduced income due to patients' use of home testing devices. Lowell Levin writes there may be some protecting of professional (for which, in many areas, read 'financial') power preserves behind the failure of many physicians to encourage self-care. Lowell Levin, *Self-Care in Health: Potentials and Pitfalls*, World Health Forum vol. 2 at 177, 177 (1981). Similarly, Mark Fuerst notes that doctors must wonder..., about the financial impact of home medical testing, as over-the-counter kits bite into what was once a physician-controlled arena. *Id.* Nevertheless, a thorough reading of the literature leaves the reader with the sense that the criticisms of home testing made by members of the medical professions primarily stem from concerns that the products may lead both to the obtainment of inaccurate results and to delayed treatment.

⁸⁴ See Lisa Iannucci, *The Perplexities of Pregnancy*, FDA Consumer, Nov. 1990, at 16; Thomas A. Gossel, *supra* note 2. at 1121.

detection. Most manufacturers, however, recommend repeating the test if the user obtains a negative result, since it may be a few days before a woman produces HCG at a detectable level.

Notwithstanding the above, home pregnancy tests are generally considered error free when performed by experienced professionals. The criticisms of home pregnancy tests generally concern the accuracy of results obtained and interpreted by laypersons. A study was conducted, in 1989, that analyzed the reliability of home pregnancy tests used by laypersons.⁸⁵ Jocelyn Hicks, Ph.D., and Mariet Iosefsohn, M.S., collected 200 urine samples from urban adolescents. They divided each specimen into two portions, one to be tested by experienced clinical chemistry technologists using Tandem Icon II and Surecell, two pregnancy tests marketed for professional use, and the other portion to be tested by nonprofessionals using the e.p.t plus and Advance home pregnancy test kits. The experienced technologists achieved identical results regardless of the laboratory device used.⁸⁶ The non-professionals, however, achieved discrepant results for 9.5% of the results obtained with e.p.t plus and 12.5% of

⁸⁵ Jocelyn M. Hicks, Ph.D., and Mariet Iosefsohn, M.S.,

Reliability of Home Pregnancy-Test Kits in the Hands of

Laypersons, 320 New Eng. J. Med. 320, 320-21 (1989). ⁸⁶ This study was written up as a letter to the editor in The

New England Journal of Medicine. Researchers Hicks and Iosefsohn do not state the explanation given the participating technologists for the purpose of the study. Thus, it is theoretically possible that some of the technologists may have known it was a comparative study and tempered their results in accordance with the researchers' hypothesis.

the results obtained with Advance. Hicks and Iosefsohn concluded that layperson difficulties in using the kits and interpreting the results caused the discrepant results.⁸⁸ They concluded that better accuracy is available in good professional laboratories and questioned whether home pregnancy tests should be marketed at all.⁸⁹

Similarly, a recent French study found that home pregnancy tests are prone to inaccurate results, specifically false-negative results.⁹⁰ At the time of the study, French law did not provide for strict regulation of home testing devices. Therefore, it is possible that a great number of the pregnancy tests used in the study would not be approvable in the United States. Nevertheless, the study is useful in illustrating the prevalence of layperson error.

In the French study, the laypersons correctly found almost all the negative urine specimens to be negative.⁹¹ However, they falsely interpreted 230 of the 478 positive urine samples as negative.⁹² Thus almost half of the positive urine samples were inaccurately found by the laywomen participating in the test to be negative. Unlike some other studies, the French study found that neither age, professional activity, nor education had a significant

⁸⁷ Hicks & Iosefsohn, *supra* note 85, at 320.

⁸⁸ *Id.*

⁸⁹ *Id.* at 321.

⁹⁰ Joelle Daviaud et al., *Reliability and Feasibility of Pregnancy Home-Use Tests: Laboratory Validation and Diagnostic Evaluation by 638 Volunteers*, 39 *Clinical Chemistry* 53 (1993) ~ *Id.* at 56.

⁹² *Id.*

Id. at 57.

~ *Id.* at 58.

~ *Id.*

influence on layperson ability to accurately conduct the test and interpret the results.⁹³

The researchers attributed the high rate of false negatives to user difficulty in interpreting the instructions for analyzing the results.⁹⁴ Over half the women did not understand one or more words appearing in the instructions. Ninety-three percent said they were satisfied with the instructions. The researchers thought, however, that the instructions could have been improved. They noted that several of the laypersons participating in the study

indicated that the leaflet in most of the kits was too long and did not provide enough information to interpret the results correctly. In particular, the illustration of the results in the leaflet did not always correspond to the actual appearance of the results.⁹⁵

Presumably, therefore, improved instructions would have led to an increase in the rate of accuracy achieved by the laywomen.

Experts generally agree that the benefits of home pregnancy testing far outweigh the negatives for the reason that early detection using the kits leads to early prenatal care. The consequences of obtaining inaccurate results, however, are likely to be significant. False positives cause emotional turmoil both for women who do not wish to be pregnant and for women who desire a child but later learn they are not pregnant. False negatives lead to delayed

physician-patient contact. Women who have falsely tested negative will not change their behavior; they will not refrain from smoking or consuming alcohol. Furthermore, pregnancy termination will become increasingly risky.

The French study underscores the importance of adequate labeling. Adequate and acceptable labeling is currently recognized by the FDA as a key factor in the safety and effectiveness of home testing products. The labeling of devices must contain adequate directions for use.⁹⁶ The FDA Center for Devices and Radiological Health guidance document states,

Inherent in the concept of adequate directions for use is the need for the labeling of home-use IVDs to be simple, concise, easy to understand, make liberal use of illustrations and drawings, use bold print or other methods to highlight warnings and precautions, and provide color coding of reagent containers whenever practicable .

The document further advised manufacturers to alert consumers to significant labeling changes by including special inserts with the device packaging which highlight key labeling changes.⁹⁸ It noted that labeling changes significantly affecting the safety and effectiveness of the device may require pre-market review and clearance prior to distribution.⁹⁹

The FDA, along with numerous other scientific researchers, has found the adequacy of home testing product

⁹⁶ 21 U.S.C. s. 352(f).

Center for Devices and Radiological Health, supra note 35, at 6.

⁹⁸ *Id.* at 10.

⁹⁹ *Id.*

labeling to be critical in ensuring that laypersons obtain accurate results. CDRH wisely suggested that manufacturers provide study participants with questionnaires to determine the effectiveness of the product labeling. ~ The FDA recommends that manufacturers provide clinical trial participants with questionnaires to determine if they understand the purpose of the test, the conditions for its use, the test's limitations, the meaning of the results and appropriate follow up. ¹⁰¹ Given the importance of effective labeling, the FDA should *require* that manufacturers use such questionnaires when conducting clinical studies. To determine whether the participants understood the instructions, the manufacturers should use questionnaires that ask them the meaning of technical or uncommon words or terms. The questionnaires might also ask them to relate the methods they used to obtain the results in order that the manufacturer may discern whether the participants used the kits properly.

Effective labeling has further been found to be critical in the context of home blood glucose meters used by laypersons to monitor blood sugar levels. Blood glucose monitors, such as the blood glucose meter used by diabetics, represent a major advance over previous methods of blood sugar monitoring which measured the spillover of sugar in urine.¹⁰² To use the meter, consumers place a drop of blood

¹⁰⁰ *See Id.* at 11.

¹⁰¹ *Id.* at 11.

¹⁰² Susan Meadows, *Improving Blood Glucose Monitoring for*

on a chemical test strip and the meter indicates the level of blood sugar. The meters are generally easy to use and are used by experienced laypersons who often must check their blood sugar several times each day. Still, inaccuracies due to layperson error do arise.¹⁰³

While self-monitoring of blood glucose (SMBG) has proved its worth for hundreds of thousands of diabetics, as of the mid-eighties there had been many complaints about inaccurate results.¹⁰⁴ Many of these inaccuracies involved user error. **105** In response to the complaints, the FDA convened a consensus conference in 1986 to determine the usefulness and efficacy of SMBG. The members of the conference concluded that use of the kits should be recommended, but that more research should be done on the adequacy and sufficiency of user education.¹⁰⁶

Subsequent studies of SMBG, conducted by the FDA, showed that when used in accordance with the directions, the kits performed accurately. However, approximately two-thirds of the *experienced* users made significant errors largely attributable to inadequate training and limited understanding of the labeling instructions. **107** The FDA found common user errors to be the failure to follow the manufacturer's procedures, improper placement of blood on the test strip,

Diabetes, FDA Consumer, May 1990, at 32.

¹⁰³ *Id*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

the failure to calibrate the meter, failure to clean the meter, and the use of outdated chemical test strips. Other problems were caused by the requisite routine replacement of batteries and the low volume of the meter's audible tones that alert the user to the various steps in the monitoring

process. The FDA found the limited helpfulness of the

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provided instruction manuals to be a major problem. Many

of the manuals contained tiny, hard to read, print, insufficient graphics, and/or language that was especially complicated or difficult to understand. Clinical trials using questionnaires geared towards determining the adequacy of labeling, as detailed above, would likely have prevented many of the problems experienced by those who practice SMBG.

Consumer experience with blood glucose monitoring devices provides evidence that even experienced laypersons may experience difficulties using home testing products and interpreting the results of the tests. ' If crucial in assisting experienced users, effective labeling is especially

crucial for devices typically used by inexperienced and/or

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untrained consumers.

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Id.

109 Although not raised as an issue in the FDA study, it is

possible that some blood glucose meter users achieved incorrect results in part due to reduced motivation. Successful blood glucose monitoring requires that the individual be motivated. On occasion this motivation decreases with time and the individual must be repeatedly encouraged to remain motivated. See Gossel,

110 *supra* note 2, at 1121.

Within the last year, Medisense has introduced a new blood glucose monitor for home use known as Precision Q-I-D, that may reduce the number of inaccuracies due to consumer difficulty or inexpertise. The test contains

On occasion, clinical trials will show that layperson use of a home testing product is unwise. Upon evaluating the results of a clinical trial conducted by Hygeia Sciences, a manufacturer wishing to market a home screen for strep throat requiring that consumers perform a throat culture, the FDA refused to approve the device.¹ The FDA was especially concerned by the high number of false positive results obtained by the lay participants in the home study.² Parents participating in the study were given the test when they brought a child with a sore throat to a physician. The physician swabbed the child's throat for a control throat culture before the parent conducted the home test.³

Hygeia Sciences attempted to explain the high rate of false positives by arguing that upon seeing the physician conduct a throat culture, the parent assumed the child must be sick and therefore overread the results of the home test. ¹¹⁴ The FDA was not satisfied by this explanation. Hygeia Sciences proposed conducting a post-marketing study to obtain more information on accuracy and consumer response to

three-electrode Microflo test strips that protect the blood sample from adverse effects of humidity extremes and temperatures and purportedly allows 'accurate performance' in the presence of common medications and disease conditions. Unlike previous products, the 0-I-D does not require that the consumer place the meter on flat surfaces or position a hanging drop of blood on the target area of the strip to achieve an accurate reading. Finally, the device does not require cleaning. 21 Gray Sheet No. 25, Jun. 19, 1995.

¹¹¹ 15 Gray Sheet No. 32, Aug. 7, 1989.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

the results. Device center rules, however, limit the conditions set on approval recommendations to those that are relatively minor. FDA officials considered the condition that a post-marketing study be performed to gauge consumer accuracy and response to exceed the range of possible conditions on an approval recommendation.^{1,5}

The results of the Hygeia Sciences study showed an especially high false positive rate. Conversely, a second study, conducted by independent medical experts, found a high rate of false negatives when inexperienced parents attempted to conduct a throat culture on their children.⁶ The researchers provided the parents of children with symptoms of Group A strep with swabs, wooden tongue depressors for collecting throat cultures, instruction sheets, and diagrams of the mouth and pharynx. A health professional then collected a second throat culture as a control. The study showed no false positives. However, for the youngest children, specifically those between the ages of four and eight, 38% of the negative results obtained by parents were false.⁷ The researchers expressed reservations with regard to the ability of parents to obtain adequate throat culture specimens from children between the ages of four and eight.

~ *Id.*

116 Michael A. Fragoso et al., *Can Parents Do a Throat Culture?*, *Pediatric Infectious Disease Journal*, December 1989, at 845.

117 *Id.* at 846. The researchers limited the applicability of

their findings and conclusions to this youngest age group since it is the only group for which there was a statistically significant number of children.

118 *Id.* at 847.

They concluded that home tests for GABS [Group A Betahemolytic Streptococcus] infection should be avoided.⁸ Under the proposed approach, it may be expected that approval would be denied as well. The results of the home studies indicate that the device would fail to satisfy the LARS.

The FDA should consider any home testing device that fails to satisfy the layperson accuracy standard to be presumptively ineffective. The presumption should be a strong presumption that may be rebutted only where the introduction of the device would nevertheless present a significant benefit to public health. Thus, failure to satisfy the LARS, although critical, need not be fatal. The presumption must be rebuttable in order that home testing devices which present a significant benefit to public health may be approved even if they fail to satisfy the accuracy standard and thus involve a greater risk of producing false results when used by laypersons. Examples of situations in which the manufacturer might rebut the presumption include situations where even professional use only tests do not satisfy the standard, no other test, including a professional use test, is available that performs the function of the home test, or the number of consumers expected to use the device is so great that its availability will lead to a significant overall increase in the number of people correctly testing positive for the disease or condition.

One example of a home testing product for which such a significant health benefit might be found is the home colorectal cancer screening kit. Colorectal cancer kits screen for hidden blood in stool, an early indication of colorectal cancer. The consumer brings a stool specimen into contact with filter paper treated with peroxide and guaiac, a chemical sensitive to blood.⁹ The presence of blood causes the filter paper to change in color. Since bleeding caused by colorectal cancer is often intermittent, the test must be repeated on subsequent bowel movements following a negative result. Moreover, the colorectal tests currently available are susceptible to several interferences that cause inaccurate results. Incorrect results may arise from the presence of non-cancer related bleeding. Drug and dietary intake may affect the results; consumers are advised to avoid red meat, turnips, horseradish, melon, vitamin C, aspirin, anti-inflammatory drugs, products containing iron, rectal

ointments, and suppositories, etc. for several days prior to

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using the kits. As one may expect, the results of

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A Consumer's Guide to Home Medical Tests, FDA Consumer, Feb. 1986, at 25. The colorectal cancer kits differ somewhat in user procedure. The Detecatest and Hemoccult tests both require that the consumer use the provided stool collection stick to place the stool specimen on a slide. The Early Detector test requires that the consumer pat the provided paper on the anal area and then spray the paper with the provided solution. The Coloscreen Test, the least unpleasant of the tests, includes a treated pad that the consumer drops into the toilet following a bowel movement. See *Counseling Patients on In-Home Colorectal Cancer Detection Kits*, Am. Pharmacy, Feb. 1987, at 59.

120 *Counseling Patients on In-Home Colorectal Cancer*

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colorectal home kits are often inaccurate. One study found that fecal occult blood testing (testing for hidden blood in the stool) failed to detect colorectal cancer about 62% of the time¹²¹

The FDA properly approved the colorectal tests despite fairly low accuracy rates. Colorectal cancer is the second most common type of internal cancer in the United States.¹²² The American Cancer Society (ACS) recommends that every individual over age 40 have a digital rectal examination each year. ACS recommends that individuals begin annual testing for fecal occult blood and periodic sigmoidoscopic exams at age 50. The availability of colorectal kits leads to an overall increase in the early detection of the cancer, since in addition to the likelihood that individuals will use the home test kits when they would not otherwise see a physician, the fecal occult blood tests allow for the detection of bleeding throughout the gastrointestinal tract whereas the

digital rectal and sigmoidoscopic exams test a more limited

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part of the digestive system. The expected overall

increase in early detection of colorectal cancer prompted the FDA to approve the kits despite the possibility that consumers might substitute the use of the kits for consultation with a physician.

Detection Kits, *supra* note 119, at 62.

¹²¹ *Home Test Kits: Left to Our Own Devices*, Harvard Health Letter, Nov. 1, 1995.

¹²² *Counseling Patients*, *supra* note 119.

¹²³ *Id*

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Analyzed under the proposed approach, the colorectal cancer kits would probably fail to satisfy the LARS. Nevertheless, given the special circumstances involved, namely the fact that the kits can detect bleeding throughout the gastrointestinal tract and the high incidence of the disease, one would expect the FDA to find that the kits were able to successfully rebut the presumption that they are ineffective and to show that they would provide significant benefit to public health.

The colorectal cancer testing products are screening devices. Screening devices permit consumers to screen themselves for unexpected conditions or diseases for which consumers are asymptomatic. Thus, screening devices may be distinguished from diagnostic devices which enable consumers to diagnose suspected diseases or conditions and from monitoring devices, such as home cholesterol kits and blood glucose kits, which enable consumers to monitor ongoing conditions. Health professionals have expressed greater concern over diagnostic tests than screening or monitoring tests, since the former are more likely to be used by individuals with symptoms of a certain condition or disease who are using the test prior to (or instead of) consulting a physician for diagnosis.²⁴ Diagnostic devices are often used by consumers in place of visits to a physician. The results of such home tests generally substitute for the results of tests conducted by physicians or other health

¹²⁴ See *Office of Inspector Gen.*, *supra* note 40, at 1.

professionals. Conversely, home screens are generally used by those who would not otherwise consult a physician.

Since home screens most often represent increased, rather than substituted, health care, the FDA has approved screening devices, such as the colorectal cancer kits, that achieve lower rates of accuracy than would ordinarily be required. Similarly, home testing screens may be more likely than diagnostic or monitoring devices to effectively rebut the LARS presumption since by providing increased, rather than substituted, health care, they may show the significant increase in public health necessary for a successful rebuttal of the presumption. In this context, the FDA should consider the availability of alternative tests, the accuracy rate actually achieved by the screen, the current prevalence of physician consultation, and the importance of early detection. A consideration of these factors would lead to approval of the colorectal kits for the reasons stated above.

Unlike the colorectal screen, the HIV blood collection kits would, in all likelihood, satisfy the LARS. Early FDA consideration of the kits questioned the accuracy of the results. This concern primarily involved the ability of laypersons to conduct the finger-prick and obtain an uncontaminated blood sample of the proper size. In comments filed with the FDA in 1989, the American Society for Medical Technology (ASMT) presented its view that the finger-prick method was unreliable when performed by laypersons..²⁵ ASMT

125 15 Gray Sheet No. 20, May 15, 1989.

detailed the complexity involved in obtaining a proper sample. It explained,

In order to ensure a 'clean' drop of blood and to guarantee that the patient is not infected by microorganisms on the surface of the skin, the finger should be cleansed immediately before and after the finger-stick to eliminate the possibility of contamination from sources exterior to the blood stream.

[Additionally] the depth of the stick will determine whether or not the drop of blood is a 'good' or representative sample... The size of the hole created by the stick, and whether or not the individual squeezes the finger to force a sizable droplet of blood out will affect the quality and density of the blood sample. When squeezed, tissue fluid from the finger may dilute the blood and prevent obtaining a representative sample.¹²⁶

Many FDA officials at one time shared this concern.¹²⁷ As with other home testing products, the dangers of

inaccurate HIV test results are great. False negatives prevent infected individuals from seeking proper medical care and lead them to engage in activities whereby they may infect others. False positives cause extreme emotional trauma to those who believe they are infected with HIV. Although not addressed in the literature, false positives create the added danger that an unknowingly seronegative individual will engage in unprotected sex with an HIV-positive partner and thereby become infected.

The argument that laypersons lack the competency to obtain a proper blood sample has not been strenuously raised for a number of years. Presumably this is due to the

¹²⁶ *Id.* It is unclear why ASMT stated the finger should also be washed after the finger-stick.

¹²⁷ 15 Gray Sheet No. 15, Apr. 10, 1989.

availability of numerous over-the-counter devices that require laypersons to conduct similar finger-pricks.¹²⁸ Under the proposed approach, the FDA would determine, by evaluating clinical trials and participant questionnaires, whether the kits satisfy the layperson accuracy rate. Given that the test merely requires the performance of a finger-prick and not the interpretation of the results, one should expect the kits to satisfy the standard so long as the package labeling is carefully prepared.

Should the kits fail to satisfy the accuracy standard, however, the manufacturers could obtain FDA approval by demonstrating a significant benefit to public health. This benefit could be shown by demonstrating the potential of the kits to curb the spread of AIDS. Many believe that the availability of home tests will lead to an increase in the number of people tested for the virus. Former Surgeon General C. Everett Koop has referred to the device as the single most important weapon that we could employ to fight

AIDS. 129

Increased testing will lead individuals infected with the virus to seek early medical treatment and will enable them to prevent the spread of the virus. Half a million people are positive for HIV and don't know it, says Sean Strub, the publisher of POZ, a magazine for HIV-positive

128 Devices that require the performance of a finger-prick include cholesterol tests and blood glucose meters.

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FDA Reverses Stand on Home Testing for HIV Virus,

National Public Radio, Morning Edition Jun. 23, 1994. Transcript available on Westlaw.

individuals.¹³⁰ One consequence of their ignorance is that they do not obtain the proper medical care. Furthermore, they do not know to refrain from activities which may cause others to become infected. Strub agrees that expanded testing is necessary to prevent transmission of the virus and supports FDA approval of the home test as a means of saving lives.

- In a study conducted by AIDS researchers at the University of California at San Francisco, the researchers found that sixty percent of those in America, considered to be at risk for AIDS, have never been tested.¹³² They defined those at higher risk for AIDS as men who have sex with men, intravenous drug users, prostitutes, hemophiliacs, those who had blood transfusions between 1977 and 1985,¹³³ and their sex partners. Forty percent of that group indicated that they would probably use the HIV blood collection kits if they were available over-the-counter.¹³⁴ Twenty nine percent of Americans in general indicated that they might use the kits.¹³⁵ The potential of HIV blood collection kits to thus slow the spread of the virus represents a truly significant benefit to public health and should successfully rebut an FDA presumption.

¹³⁰ Marwick, *supra* note 61.

¹³¹ *Id.*

¹³² Sabin Russell, *UC Researchers Urge Home Tests for AIDS*, S.F. Chron., May 11, 1995, at A7.

¹³³ *Id.*

¹³⁴ *Id.*

Id.

¹³⁵ *Id.*

Once the FDA establishes that a home testing device either satisfies the accuracy standard or shows a significant benefit to health such that it rebuts the presumption that the device is ineffective for failing to satisfy the standard, the FDA should end its inquiry and approve the device. At this point, the FDA should consider neither whether consumers will subsequently consult a physician nor whether consumers will intentionally injure themselves upon testing positive for a disease or condition.

The FDA should not consider whether consumers will subsequently consult a physician. The agency should require all home testing product labeling to warn that consumers who continue to experience symptoms or otherwise feel ill should consult a physician, however, approval should not be denied because treatment may be delayed. Those falsely testing negative for a disease or condition are likely experience a worsening of their state of health due to the delay in treatment. Death may result from this delay in treatment. This, of course, would be a tragedy. However, by establishing an accuracy standard and a rebuttable presumption that products not satisfying the standard will not be approved, the system works to limit the number of tragedies caused by false negatives so that they are greatly outweighed by the number of people who correctly test positive and would not have otherwise been tested. It accepts the possibility of some delayed treatment caused by

false negatives in exchange for an overall increase in accurate testing.

Furthermore, the FDA should not deny approval because of fears that consumers correctly testing positive for a disease or condition may fail to consult their physician. By purchasing a home testing product and thereafter using the product, the user indicates both a concern for and a desire to maintain her health. Steven Salbu argues,

Individuals administer home tests because they are concerned about the state of their health; there is no rational basis for assuming that the recipient of positive test results is less likely to seek treatment or medical advice than the person who has not engaged in home testing. Moreover, because home testing expands access to vital information, the net number of persons in need of medical care who seek and receive that care is likely to expand rather than decrease.¹³⁶

Thus, one may expect consumers testing positive for a disease or condition to consult a physician upon obtaining a positive test result.

Additionally, the FDA should not consider whether consumers will intentionally injure themselves upon testing positive for a disease or condition. The risk that a consumer will intentionally injure him or herself is an issue of secondary safety and should not be a factor in the approval process. Steven Salbu refers to secondary safety risks as the risks associated with reactions to the safe use of an effective product, as opposed to primary safety risks which are those associated immediately and directly with a

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Steven Salbu, *HIV Home Testing and the FDA: The Case for Regulatory Restraint*, 46 Hastings L.J. 403. 418 (1995)

product that in itself is ineffective or unsafe.’ A primary safety risk is the risk that a device such as the Relaxicisor will send shocks through the body, while a secondary safety risk is the risk that the consumer will intentionally injure herself. Stated differently, primary safety risks directly result from the use of the medical device, while secondary risks require supervening user actions.

Neither the Medical Device Amendments nor its legislative history directly addresses the question whether the FDA should consider secondary risks of safety. An inference is properly drawn from the legislative history, however, that Congress did not intend the FDA to use its regulatory authority to limit the availability of devices that show primary safety and effectiveness. The passage of the Medical Device Amendments was prompted by the Dalkon Shield tragedy which resulted from the primary unsafety of the device. ¹³⁸ As discussed above, the Senate Report contains numerous examples of unsafe or quack devices that reached the public because of the lack of FDA authority to require that all medical devices are safe and effective before they are allowed in the marketplace.¹³⁹ None of the cited examples concerned issues of secondary safety. This properly leads to an inference that the Medical Device Amendments were enacted to combat the problem of primarily unsafe devices only.

¹³⁸ *Id.* at 449-50.

¹³⁹

See generally, S. Rep. No. 33.

¹³⁹ *Id.*

Strong policy reasons exist to limit the applicability of the statute to issues of primary safety. Peter Huber writes that barring reliable diagnostic information because it might badly frighten someone is unconscionable in a free society. ¹⁴⁰ In arguing that the FDA should approve the HIV home blood collection kits, Huber claims,

The very thought that we should limit when and how people learn vitally important things about their own health, just because they might otherwise rush to the arms of Dr. Kevorkian, seems murderously paternalistic. Sure, knowledge has its perils. But not knowing is more dangerous. ¹⁴¹

Issues of secondary safety should not be considered both because not knowing is more dangerous *and* because we should not limit when and how people who seek vitally important information about their health obtain that information.

In considering whether to approve HIV blood collection kits, the FDA was extremely concerned that a secondary safety risk existed. The FDA feared that consumers might commit suicide upon testing positive for the virus. ¹⁴² Salbu correctly criticized the FDA for using its power to withhold pre-market approval of HIV home test kits due to this concern.

Many once believed that HIV blood collection kits should not be approved because those testing positive for the virus might commit suicide if face to face counseling was not provided immediately. A 1988 study conducted by researchers

¹⁴⁰ Peter Huber, *Blood Tests*, Forbes, Aug. 1, 1994, at 97.

¹⁴¹ *Id.*

¹⁴² See generally, Salbu, *supra* note 136.

¹⁴³ *Id.* at 447.

at the Cornell University Medical College Laboratory of Psychopharmacology and New York's Office of Chief Medical Examiner did find an alarmingly high risk of suicide among persons suffering from AIDS.¹⁴⁴ The study looked at suicides among New York City residents during the 1985 calendar year. While the general rate of suicide among men aged 20 to 59 years, the group then most at risk for AIDS, was 18.75 deaths per 100,000, the suicide rate among the men aged 20 to 59 who had been diagnosed as suffering from AIDS was 680.56 deaths per 100,000.¹⁴⁵ The researchers found the relative risk of suicide in men with AIDS of the relevant age category to be 36 times that of men without AIDS.¹⁴⁶ Apparently, the majority of the suicides were AIDS related; the researchers found evidence that the suicide victims were aware that they suffered from AIDS.¹⁴⁷ The study concluded that AIDS represents a significant risk factor for suicide.¹⁴⁸ It further concluded that recent advocacy of mass population HIV-antibody screening should be viewed cautiously, unless appropriate counseling can be offered concerning the ramifications of the illness and the significance of the test results. „¹⁴⁹

¹⁴⁴ Peter M. Marzuk et al., *Increased Risk of Suicide in Persons with AIDS*, 259 JAMA 1333 (1988).

~ Note that the actual number of suicides by men in this age category was twelve, leading one to question the reliability of the researchers' findings.

¹⁴⁶ Marzuk et al., *supra* note 144.

¹⁴⁷ See *Id.* for information regarding known suicide notes, suicide victims suffering from AIDS related depression, and suicides committed in hospitals.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

Circumstances have changed since 1985. At that time the public had very little accurate information about the AIDS virus. Instead, there was mass ignorance and paranoia. A common perception was that testing positive for the presence of the virus meant quick and certain death. Today, although AIDS is still a dreaded and feared disease, testing positive for the presence of HIV is no longer viewed as dictating immediate death or illness. A number of somewhat effective interventions, such as AZT, are now available for combating the virus. Moreover, consumers have seen that people can live with the virus for many years before becoming sick. They have seen Magic Johnson return to basketball and Greg Louganis participate in the Olympics. Consumers today know that HIV positive individuals can and do live productive lives, despite being infected with the virus. Finally, the conclusions of the New York researchers may be somewhat suspect due to the relatively small number of suicide victims.

The FDA should respect the choice of all those who wish to test themselves for a condition using a home testing product or blood collection kit. At the same time, the FDA should recognize that for many other avenues of testing may be inaccessible. For millions of Americans living in rural or isolated areas, HIV testing facilities are inaccessible. For many people, testing facilities, although seemingly accessible, are marginally inaccessible. Salbu defines home testing as marginally accessible when the individual

determines that the costs of exploiting a technically feasible option are worth bearing and marginally inaccessible when the costs are not worth bearing. He supports determining how many people would consider home testing to be marginally accessible and on-site testing marginally inaccessible as a more useful and pragmatic conception of accessibility, since this broader definition accounts for impediments that actually hinder persons from being tested.¹⁵¹ Examples of such impediments might be time constraints, child care constraints, or the lack of public transportation to and from a testing facility making it difficult to go to a clinic for on-site testing. Even if individuals can technically surmount the impediments to on-site testing, these impediments [] impair availability by reducing the ease and the net perceived utility of being tested.¹⁵² Salbu believes that [g]iven the value of testing, society cannot afford even scalable [sic] barriers to HIV-testing access.¹⁵³

A final issue that the FDA should not factor into its evaluation of home testing products is the projected price of the product. The FDA should not deny a request for approval because the poor may be unable to afford the device. Furthermore, it should not limit the device to prescription use only in order to enable the poor to be reimbursed for the

¹⁵⁰ Salbu, *supra* note 136, at n.115-16.

¹⁵¹ *Id.* at 429.

¹⁵² *Id.*

¹⁵³ *Id.*

cost of purchasing the device, since limiting the availability to prescription sale only would negate many of the product's benefits and strengths. If the product is limited to sale by prescription, the consumer must consult a doctor to obtain the prescription. Consulting a doctor involves time, money, and reduced privacy - the very things consumers seek to avoid by using home testing products. Moreover, those of the poor that are willing to consult a doctor for a prescription are likely to be the same individuals that are more willing to be tested by a doctor or at a clinic that provides anonymous testing. Consequently, even if requiring prescription sale would enable the poor to afford the kits, such a requirement represents a policy error.

Home testing products that either satisfy the accuracy standard or otherwise show a significant benefit to public health should be approved for over-the-counter sale regardless of their projected price. It is the responsibility of government, not industry, to provide health care to the poor. The FDA should not attempt to place this burden on the industrial sector by either limiting the availability of the product to prescription use or prohibiting its availability altogether.

Finally, experience has shown that as technology improves and additional manufacturers enter the market, prices are likely to fall. This has been seen in the context of home blood glucose meters where manufacturers lowered the

price of the kits when technological innovations were achieved. Also, the market can often be relied on to stabilize the cost of medical devices. It is relevant to note that ChemTrak recently lowered the price on its home cholesterol test in an effort to increase kit sales¹⁵⁴ and home pregnancy tests are now sold by different manufacturers for a wide range of prices.

The issue of price should not have been considered by the FDA during its consideration of HIV home blood collection kits. A number of panelists on the Blood Products Advisory Committee June 1994 panel expressed concern that with a projected price between thirty and fifty dollars, only those in the middle and upper classes would be able to afford HIV blood collection kits. ¹⁵⁵ At least one speaker at the forum noted concern that AIDS is a major problem for the poor who are unlikely to spend thirty dollars on a kit.¹⁵⁶ Panelist Robert Woodland, Ph.D., questioned whether manufacturers would provide kits at reduced rates for those unable to afford the market price.

Despite the good intentions of the panelists in expressing concern that the price will be prohibitive for many, the kits should have been approved regardless of whether the manufacturers agreed to make them available to

¹⁵⁴ 22 Gray Sheet No. 1, Jan. 1, 1996.

¹⁵⁵ 20 Gray Sheet No. 26, Jun. 27 1994.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* Apparently, participants did not consider the possibility, discussed above, of making the product available by prescription only.

the poor at reduced prices. The FDA should not preclude the public from using a medical device because the price may be prohibitive to some.

Conclusion

With FDA approval of HIV blood collection kits still pending, the time is ripe for the agency to espouse a new approach in evaluating home testing products. The FDA should use its considerable discretion to approve home testing devices that, when used by laypersons, produce results that are sufficiently accurate. The FDA should consider the devices to be sufficiently accurate when they satisfy an FDA home testing device accuracy standard where the achievement of higher rates of layperson accuracy is not feasible or when they provide a significant public health benefit despite the lower rates of accuracy. Manufacturers should be required to provide evidence that consumers are able to accurately evaluate the test results and understand the labeling instructions and warnings. This approach would result in the approval of safe and effective devices in a more predictable and speedy manner.

Home testing products provide consumers with an additional choice in planning their health care. Consumers will decide to use or not use home devices for different reasons. Some will prefer testing themselves at home, while others may choose to be tested by professionals. Whatever

the consumer's reason for choosing to use a home testing product that provides accurate results, the FDA should work to ensure that this option is available.

It has been said that the pace of proceedings at the Food and Drug Administration... does not rival that of, say, a turn-of-the-century sweatshop in New York city. ¹⁵⁸ The proposed approach is intended to provide a simpler, more focused, and, therefore, quicker approval process. Beneficial products would be available to consumers more quickly and the FDA could make better use of its limited resources. Most importantly, the next controversial home testing or collection product to be developed would not require ten years of FDA consideration.

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Gen. Medical Co., 770 F.2d at 216, 248 U.S. App. D.C. at 160.